Attorney's Docket No.: 14875-161US1 / C1-A0313P2-US



Applicant: Kunihiro Hattori et al.

Serial No.: 10/575,905

Filed: April 14, 2006

Art Unit: Unknown

Examiner: Unknown

Conf. No.: 2076

Title : BISPECIFIC ANTIBODIES SUBSTITUTING FOR FUNCTIONAL PROTEINS

## MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. A copy of the listed U.S. patent can be provided upon request. Also enclosed are copies of an International Search Report and an International Preliminary Report on Patentability from a counterpart application (PCT/JP2003/013123).

Translations of non-English references AC, AJ, AL, AN, and AO are not included, since they are members of the patent families of English language references AB, AP, AR, AS, and AU, respectively. English translations are provided for references AW and AX, and English machine translations are provided for references AE-AI, AK, and AM. An English abstract is provided for reference AD. Reference AXX provides a concise English explanation of reference AGGG.

Applicants wish to bring to the Examiner's attention co-pending and co-owned non-provisional application serial number 10/575,193 (Attorney Docket No. 14875-160US1), which concerns related subject matter and has overlapping inventorship with the above-referenced application. Applicants assume that the Examiner has ongoing access to the file of this related application and can obtain copies of prosecution documents from the file if at any point in the

## CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Serial No.: 10/575,905 Filed: April 14, 2006

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future he/she considers it potentially relevant to issues in the present application. Applicants will supply copies of such documents from the related application's file, should the Examiner request them.

This statement is being filed before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 14875-161US1.

Respectfully submitted,

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Substitute Form PTO-1449 (Madified)

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 14875-161US1

Application No. 10/575,905

by Applicant
(Use several sheets if necessary)

Applicant Kunihiro Hattori et al.

Filing Date April 14, 2006 Group Art Unit Unknown

CH TRADE	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,474,893	10/02/1984	Reading			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Desig.		Document	Publication	Country or			Transl	
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AB	CA 2 019 559	12/22/1990	Canada				
	AC	EP 0 404 097 `	12/27/1990	EPO			See AB	
	AD	JP 2-145187 '	06/04/1990	Japan			English abstract	
	AE	JP 5-184383	07/27/1993	Japan			X	
	AF	JP 5-199894	08/10/1993	Japan			х	
	AG.	JP 5-203652	08/10/1993	Japan			х	
	AH ·	JP 5-213775	08/24/1993	Japan			х	
	AI.	JP 5-304992	11/19/1993	Japan			Х	
	AJ ·	JP 5-501543	03/25/1993	Japan			See AP	
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	AM ·	JP 11-71288	03/16/1999	Japan			Х	
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	AQ -	WO 93/11161`	06/10/1993	WIPO				
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	AS '	WO 96/26964 ,	09/06/1996	WIPO				
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	AV٠	WO 01/19992 ·	03/22/2001	WIPO				
	AW.	WO 03/087163	10/23/2003	WIPO			X	
	AX-	WO 2004/065611	08/05/2004	WIPO			X	

Exam	iner	Signa	ture

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 14875-161US1	Application No. 10/575,905	
	losure Statement plicant	Applicant Kunihiro Hattori et al.		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date April 14, 2006	Group Art Unit Unknown	

Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner	Desig.	_		
Initial	ID	Document		
	AY	Bebbington et al., "High-Level Expression of a Recombinant Antibody from Myeloma Cells Using a Glutamine Synthetase Gene as an Amplifiable Selectable Marker," <i>Biotechnology (N Y)</i> , 10:169-175 (1992)		
	AZ	Bos et al., "Enhanced Transfection of a Bacterial Plasmid into Hybridoma Cells by Electroporation: Application for the Selection of Hybrid Hybridoma (Quadroma) Cell Lines," <i>Hybridoma</i> , 11:41-51 (1992)		
	AAA	Brennan et al., "Preparation of Bispecific Antibodies by Chemical Recombination of Monoclonal Immunoglobulin G1 Fragments," <i>Science</i> , 229:81-83 (1985)		
	ABB	Carter, "Bispecific human IgG by design," J. Immunol. Methods, 248:7-15 (2001)		
	ACC	Deng et al., "An Agonist Murine Monoclonal Antibody to the Human c-Mpl Receptor Stimulates Megakaryocytopoiesis," <i>Blood</i> , 92:1981-1988 (1998)		
	ADD	Francois et al., "Construction of a Bispecific Antibody Reacting with the $\alpha$ - and $\beta$ -Chains of the Human IL-2 Receptor," J. Immunol., 150:4610-4619 (1993)		
	AEE	GenPept Accession No. AAC26541, "anti BoNT/A Hc scFv antibody [synthetic construct]," 1 page (August 1, 2001)		
	AFF	Hämmerling et al., "Use of Hybrid Antibody with Anti-γG and Anti-Ferritin Specificities in Locating Cell Surface Antigens by Electron Microscopy," J. Exp. Med., 128:1461-1473 (1968)		
	AGG	Holliger et al., "'Diabodies': Small bivalent and bispecific antibody fragments," <i>Proc. Natl. Acad. Sci. USA</i> , 90:6444-6448 (1993)		
	АНН	Huse et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," Science, 246:1275-1281 (1989)		
	AII	Kang et al., "Linkage of recognition and replication functions by assembling combinatorial antibody Fab libraries along phage surfaces," <i>Proc. Natl. Acad. Sci. USA</i> , 88:4363-4366 (1991)		
	AJJ	Karpovsky et al., "Production of Target-Specific Effector Cells Using Hetero-Cross-Linked Aggregates Containing Anti-Target Cell and Anti-Fcγ Receptor Antibodies," <i>J. Exp. Med.</i> , 160:1686-1701 (1984)		
	AKK	Kim et al., "Mammalian type I interferon receptors consists of two subunits: IFNaR1 and IFNaR2," Gene, 196:279-286 (1997)		
	ALL	Kroesen et al., "Phase I study of intravenously applied bispecific antibody in renal cell cancer patients receiving subcutaneous interleukin 2," Br. J. Cancer, 70:652-661 (1994)		
	AMM	Kurokawa et al., "Enhanced Fibrinolysis by a Bispecific Monoclonal Antibody Reactive to Fibrin and Tissue Plasminogen Activator," <i>Bio/Technology</i> , 7:1163-1167 (1989)		
	ANN	Lapan et al., "Interaction of the A1 Subunit of Factor VIIIa and the Serine Protease Domain of Factor X Identified by Zero-length Cross-linking," Thromb. Haemost., 80:418-422 (1998)		
	AOO	Le Doussal et al., "Bispecific Monoclonal Antibody-Mediated Targeting of an Indium-111-Labeled DTPA Dimer to Primary Colorectal Tumors: Pharmacokinetics, Biodistribution, Scintigraphy and Immune Response," J. Nucl. Med., 34:1662-1671 (1993)		
	APP	Link et al., "Production and Characterization of a Bispecific IgG Capable of Inducing T-Cell-Mediated Lysis of Malignant B Cells," <i>Blood</i> , 81:3343-3349 (1993)		
	AQQ	Löfqvist et al., "Haemophilia prophylaxis in young patients – a long-term follow-up," J. Intern. Med., 241:395-400 (1997)		

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no	t in conformance and not considered. Include copy of this form with
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 14875-161US1	Application No. 10/575,905	
Information Disclo by App		Applicant Kunihiro Hattori et al.		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date April 14, 2006	Group Art Unit Unknown	

Other Documents (include Author, Title, Date, and Place of Publication)					
Examiner	Desig.				
Initial	ID	Document			
	ARR	Lu et al., "Di-diabody: a novel tetravalent bispecific antibody molecule by design," J. Immunol. Methods, 279:219-232 (2003)			
	ASS	Lu et al., "Fab-scFv fusion protein: an efficient approach to production of bispecific antibody fragments," J. Immunol. Methods, 267:213-226 (2002)			
	ATT	Massino et al., "Quantitative analysis of the products of IgG chain recombination in hybrid hybridomas based on affinity chromatography and radioimmunoassay," <i>J. Immunol. Methods</i> , 201:57-66 (1997)			
	AUU	McCafferty et al., "Phage antibodies: filamentous phage displaying antibody variable domains,"  Nature, 348:552-554 (1990)			
	AVV	Mertens et al., "Factor VIII-Factor IX Interactions: Molecular Sites Involved in Enzyme-Cofactor Complex Assembly," <i>Thromb. Haemost.</i> , 82:209-217 (1999)			
	AWW	Milstein et al., "Hybrid hybridomas and their use in immunohistochemistry," <i>Nature</i> , 305:537-540 (1983)			
	AXX	"National Haemophilia Foundation (NHF) Medical and Scientific Advisory Council (MASAC) Recommendations Concerning Prophylaxis," Medical Bulletin, No. 193, 1 page (1994)			
	AYY	Nilsson et al., "Twenty-five years' experience of prophylactic treatment in severe haemophilia A and B," J. Intern. Med., 232:25-32 (1992)			
	AZZ	Nitta et al., "Preliminary trial of specific targeting therapy against malignant glioma," Lancet, 335:368-371 (1990)			
	AAAA	Ridgway et al., "'Knobs-into-holes' engineering of antibody C <sub>H</sub> 3 domains for heavy chain heterodimerization," <i>Protein Eng.</i> , 9:617-621 (1996)			
	ABBB	Segal et al., "Introduction: bispecific antibodies," J. Immunol. Methods, 248:1-6 (2001)			
		Shalaby et al., "Development of Humanized Bispecific Antibodies Reactive with Cytotoxic Lymphocytes and Tumor Cells Overexpressing the <i>HER2</i> Protooncogene," <i>J. Exp. Med.</i> , 175:217-225 (1992)			
-	ADDD	Stickney et al., "Bifunctional Antibody: A Binary Radiopharmaceutical Delivery System for Imaging Colorectal Carcinoma," Cancer Res., 51:6650-6655 (1991)			
	AEEE	Suresh et al., "Advantages of bispecific hybridomas in one-step immunocytochemistry and immunoassays," <i>Proc. Natl. Acad. Sci. USA</i> , 83:7989-7993 (1986)			
	AFFF	Suresh et al., "Bispecific Monoclonal Antibodies from Hybrid Hybridomas," <i>Methods Enzymol.</i> , 121:210-228 (1986)			
Taki, The Journal of Japanese Society on Thrombosis and Hemosta.		Taki, The Journal of Japanese Society on Thrombosis and Hemostasis, 13:109-113 (2002) (see reference AXX for concise English explanation)			
	АННН	Weiner et al., "A Human Tumor Xenograft Model of Therapy with a Bispecific Monoclonal Antibody Targeting c-erbB-2 and CD16," Cancer Res., 53:94-100 (1993)			
	AIII	Weiner et al., "The Role of T Cell Activation in Anti-CD3 × Antitumor Bispecific Antibody Therapy," J. Immunol., 152:2385-2392 (1994)			
,	AJJJ	Xiang et al., "Production of Murine V-Human Cr1 Chimeric Anti-TAG72 Antibody Using V Region cDNA Amplified by PCR," Mol. Immunol., 27:809-817 (1990)			

Examiner Signature	Date Considered
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